# PHARMACARE NEWSLETTER



March 21, 2001
01-04

*Web site:* http://www.hlth.gov.bc.ca/pharme/index.html

*PLEASE CIRCULATE AMONG DISPENSING STAFF*

## CORRECTIONS:

**Newsletter 01-01 Page #2 Benefits table:**

Din 2241820 PMS-Vancomycin (vancomycin HCL) vial "50mg" should read "500mg".

**Newsletter 01-02 Page 3:**

Spelling error "M-Elson" should read "M-Eslon"

Benefits table: Tarocort 0.2% cream (DIN 02242984) and ointment (DIN 02242985) should read "Y" under Eligible for Palliative Care.

Benefits table: Baycol (DIN 02243223) is not eligible for Plan G nor for Palliative Care benefits.

**Newsletter 01-03**

Please note that the number of this newsletter should read "01-03", and not "00-03".

## UPDATE ON PHARMACARE COVERAGE OF TETRABENAZINE

Nitoman® (tetrabenazine) manufactured by Hoffman La Roche is currently not available in Canada. As a result, tetrabenazine is now only available through Health Canada's Special Access Program. We have been advised that this is a temporary situation.

Under these circumstances, PIN 66124050 has been assigned and should be used when dispensing tetrabenazine 25mg tablets. A Special Authority will be required for benefit coverage, because the product is currently special access.

## DISULFIRAM (ANTABUSE®) SHORTAGE

Pharmacare has been advised that Antabuse® manufacturered by Wyeth Ayerst is not commercially available until further notice. Therefore, Pharmacare will provide coverage for compounded Disulfiram 250mg and 500mg capsules.

Please submit claims for coverage using the assigned PINS 66124085 (Dilsulfiram 250mg) and 66124087 (Disulfiram 500mg) only. Coverage for the compounded products will be discontinued once supply by Wyeth Ayerst is available.

## DISPENSING FEES

We frequently receive reports of pharmacies discounting dispensing fees to customers, in particular seniors. This is to remind pharmacy managers that the fee claimed to Pharmacare is no greater than that made to any person or agency. Please refer to 1.h) of your PHARMACY PARTICIPATION AGREEMENT for further clarification.

## UPDATE ON COVERAGE OF BUTORPHANOL NASAL SPRAY

Effective March 30, 2001, Pharmacare coverage for butorphanol nasal spray will be limited to the 30 day supply policy. Please note that this restricted benefit will only be covered on a prior approval basis, according to the eligibility and deductibility of the patient's Plan. In addition, special authorities will be subject to the LCA policy, whereby Apo-butorphanol (DIN 2242504) is fully covered, and Stadol® (DIN 2113031) is subject to partial coverage.

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## REMINDER OF RECORD REQUIREMENTS

Pharmacy managers are reminded that compliance with Pharmacare policy is required to substantiate claims payments.

Under the Pharmacy Participation Agreement, the pharmacy is required to abide fully by the policies and procedures of the Program as stated by Pharmacare. This includes all requirements, including record-keeping requirements, of the British Columbia College of Pharmacists, the *Pharmacy Operations and Drug Scheduling Act*, the Food and Drugs Regulations (Canada) and any other federal and provincial requirements. Pharmacare payments that are unsubstantiated are subject to recovery by the Ministry of Health.

In particular, the following excerpts are provided for your convenience:

1) Records Retention:

Bylaw 35(5) of the Bylaws of the Council of the College of Pharmacists of British Columbia (December 1999) states "All prescriptions and patient records must be retained for a period of not less than three years." The record must be retained for three years from the last use (refill) of the prescription, not from its creation date.

2) Recording of Refill Authorizations

College of Pharmacists' Bulletins dated January-February 2000, provides College policy for refill documentation requirements. The assignment of a new prescription number and preparation of a new hard copy prescription method listed in the Bulletin allows auditors access to the documentation without accessing the pharmacy computer. This is advantageous to the pharmacy during an onsite audit, as it minimizes the disruption to the pharmacy business.

3) Restriction of Time Span for Prescription

Bylaw 41(5) of the Bylaws of the Council of the College of Pharmacists of British Columbia (December 1999) states "The pharmacist shall restrict the time span for ongoing prescription authorization to a maximum of one year from the prescribing date."

## BLOOD GLUCOSE TEST STRIPS

*The following new blood glucose strips have been assigned PINs as indicated below for individuals who have a valid blood glucose training certificate*

| DIN | MAN | DRUG NAME |
|---|---|---|
| 44123025 | LIF | One touch ultra BG test strip |
| 44123024 | MED | Precision extra BG test strip |

## BENEFITS

*The following new products have been included as eligible Pharmacare benefits on Plans A, B, C, E and F*

| DIN | MAN | DRUG NAME | Short Term | Long Term | Plan G Eligible | Palliative Care Eligible |
|---|---|---|---|---|---|---|
| 2242485 | SIL | SAB Cortimyxin ophth ointment | Y | | | |
| 2231934 | PFR | Oxy-IR (oxycodone HCl) tabs 5mg | Y | | | Y |
| 2240131 | PFR | Oxy-IR (oxycodone HCl) tabs 10mg | Y | | | Y |
| 2240132 | PFR | Oxy-IR (oxycodone HCl) tabs 20mg | Y | | | Y |

| | | | | | | |
|---|---|---|---|---|---|---|
| 2238465 | SCH | Nasonex (mometasone furoate) nasal spray 50mcg | Y | | | |

# LCA UPDATES

## ASA EC Tab 325mg

Due to supply problems in this category, effective immediately, Westcan ASA EC Tab 325mg, din 2010526 and Stanley ASA EC Tab 325mg, din 724912, have been designated "F" Full status until further notice.

## AMENDMENTS TO LCA BOOKLET EFFECTIVE MARCH 01, 2001:

### LCA PRICE CHANGES

| CATEGORY | CURRENT LCA PRICE | NEW LCA PRICE |
|---|---|---|
| Betamethasone lotion 0.1% | 0.2011 | 0.2670 |
| Methotrexate tabs 2.5mg | 0.7212 | 0.7598 |
| Ferrous Gluconate tabs 300mg | 0.0110 | 0.0125 |
| Fluphenazine cone inj. 100mg | 26.0337 | 31.0589 |
| Morphine inj. 50mg/ml | 1.3125 | 1.9046 |

### LCA STATUS CHANGES FROM "P" PARTIAL TO "F" FULL

| | MAN | BRAND NAME |
|---|---|---|
| 2182963 | FAU | Methotrexate tabs 2.5mg |
| 0545031 | APX | Apo Ferous Gluconate 300mg |

## NEW PRODUCTS CATEGORIZED TO LCA and/or RDP

*The following new products under the Low Cost Alternative Program (LCA) / Reference Drug Program (RDP) have been included as eligible Pharmacare benefits on Plans A, B, C, E & F*

| DIN | MAN | DRUG NAME | FULL/ PARTIAL | LCA/RDP Price | Short Term | Long Term | Plan G Eligible | Eligible for Palliative Care |
|---|---|---|---|---|---|---|---|---|
| 2243127 | GPM | Gen-Lovastatin (lovastatin) tabs 20mg | P | 1.4207 | | Y | | |
| 2243129 | GPM | Gen-Lovastatin (lovastatin) tabs 40mg | P | 2.6232 | | Y | | |
| 2242798 | SIL | Sab Anuzinc HC supp | P | 0.6218 | | Y | | Y |
| 2242528 | SIL | SAB-Proctomyxin HC supp (framycetin/dibuc HCl/HC/escul) | P | 0.8322 | | Y | | Y |
| 2242527 | SIL | SAB Proctomyxin ointment | P | 6.443 | | Y | | Y |

## RESTRICTED BENEFITS

*Special Authority Only (criteria follows)*

| DIN | MAN | DRUG NAME | Short Term | Long Term |
|---|---|---|---|---|
| 2169649 | BEX | Betaseron® (interferon beta-1b) | | Y |

**Interferon beta-1b (Betaseron®), for treatement of secondary progressive multiple sclerosis (MS)**

Interferon beta-1b is currently funded for use in relapsing remitting MS. After reviewing the literature, the DBC has recommended that the MS Expert Panel continue to serve as a screening panel for patients with MS, whether it be relapsing-remitting, or secondary progressive. Coverage of interferon beta-1b in secondary progressive MS will only be considered for patients who are still experiencing relapses. The Panel will assess individual patients as they are presented and Pharmacare funding will continue to be predicated on the advice of this expert panel.

## NON BENEFITS

*Pharmacare's Drug Benefit Committee (DBC) recently completed the review of the following products and recommended that these products not be added as benefits under the program (comments follow)*

| DIN | MAN | DRUG NAME |
|---|---|---|
| 2240431 | SLO | Teveten® (eprosartan) tabs 300mg |
| 2240432 | SLO | Teveten® (eprosartan) tabs 400mg |
| 2231587 | JSO | Eprex® (epoetin alfa) sterile solution 10000iu 1.0ml |
| 2231583 | JSO | Eprex® (epoetin alfa) sterile solution 1000iu 0.5ml |
| 2206072 | JSO | Eprex® (epoetin alfa) sterile solution -iv sc 20000iu ml |
| 2242471 | PUJ | Dostinex® (cabergoline) tabs 0.5mg |
| 2232043 | PFI | Aricept® (donepezil HCl) tabs 5mg |
| 2232044 | PFI | Aricept® (donepezil HCl) tabs 10mg |
| 2238162 | ENA | Diastat® (diazepam) rectal delivery system gel 5mg ml |
| 2242367 | LLA | Visudyne® (verteporfin) vial 15mg |
| 2239630 | UNK | TOBI® (tobramycin/Na chlor 0.2%) |
| 2240775 | NVR | Miacalcin® (calcitonin salmon synthetic) nasal spray 200 iu |

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**Eprex® (erythropoeitin)**

Erythropoetin, for use in the treatment of anemia in cancer patients, will not be added as a benefit, and is not eligible for Pharmacare coverage.

**Aricept® (donepezil)**

Based on evidence from newly published double blind randomized controlled trials there was a small, 1.5-2.9 point improvement on the ADAS-cog sub scale (70 points) in patients treated with donepezil in mild-moderate Alzheimer's Disease. The clinical importance of this cognitive change has not been established.

The review of the resubmitted material completed by the DBC identified two new clinical trials (Burns, Greenberg) and two meta-analyses (Birks, Anonymous). Both trials demonstrated improvements in the ADAS-cog scores. However, in both trials there were significant gastrointestinal and CNS adverse events. In addition, there were no statistically significant changes noted in the secondary outcomes, including explicit verbal recall, verbal fluency and caregiver rating.

From a pharmacoeconomic perspective, the DBC concluded that more clinical evidence was required to assess the validity of the assumptions made in showing any potential cost effectiveness.

**Diastat® (diazepam) rectal delivery system**

Although there were two trials identified comparing diazepam rectal gel with placebo that demonstrated effectiveness, there were no published trials comparing it to compounded diazepam rectal solution in the management of patients with acute repetitive seizures. In the absence of clinical evidence for a therapeutic advantage, the DBC was unable to justify the high cost of Diastat® rectal gel when compounded diazepam rectal preparations are currently funded through the Program.

**Visudyne® (verteporfin)**

Verteporfin (Visudyne®) for use in the treatment of age related macular degeneration (AMD) of the eye is not eligible for coverage through the Pharmacare program. It has been recommended that the procedure be performed only under hospital setting. Regional Programs is currently working with the health authorities regarding the funding for this procedure through hospitals.

**TOBI® (tobramycin/Na chlor 0.2%)**

There is evidence that inhaled tobramycin provides a benefit over placebo in prophylaxis of respiratory exacerbations of cystic fibrosis. However, there is insufficient evidence at the present time that preservative-free TOBI® provides a therapeutic advantage over other available forms of tobramycin, either the ampoule containing preservatives or the multi-dose preservative-free product. In the absence of clinical evidence for a therapeutic advantage, the DBC was unable to justify the high cost of TOBI® when other forms of tobramycin are currently funded through the Program.

**Salmon-calcitonin (Miacalcin®) nasal spray**

The DBC initially reviewed calcitonin nasal spray in July 2000. Based on the review of the Overgaard trial, the DBC found that the sample size of this dose-response study was too small to detect differences in fracture rates in postmenopausal women with bone mineral density (BMD) levels at 2 standard deviation below mean values. There was no difference between the calcitonin treated groups and placebo in bone mineral density of the lumbar spine and distal forearm. The number of radiographic and clinical fractures among all groups was low. The trial was not designed to detect changes in fracture rate, and there was limited data with the recommended dose of 200IU daily.

The DBC has since reviewed the evidence from the recently published PROOF trial by Chestnut et al (*American Journal of Medicine* 2000; 109:267-276, Prevent Recurrence of Osteoporotic Fracture). In this study, although a large number of patients (n=1255) had been enrolled it did not account for sufficient patients after randomization to draw effectiveness conclusions. Chestnut et al's study had additional methodological flaws. Investigators were not blinded to BMD results, potentially compromising blinding as to group allocation and possibly affecting the composition of the patient groups completing the trial. In addition, the data was analysed for the three treatment groups, 100, 200, and 400

IU groups, without accounting for chance variation. This is strongly suggested by the absence of dose response and the finding of a statistically significant decrease for the 200 IU group alone.

## DRUGS UNDER REVIEW

*The following drug submissions are currently under review by the Therapeutics Initiative, Pharmacoeconomics Initiative and the Drug Benefit Committee of Pharmacare.*

alendronate (FOSAMAX®), resubmission
ancestim (STEMGEN®)
azithromycin (ZITHROMAX®), resubmission
botulinium toxin (BOTOX®)
desmopressin (DDAVP®) tablets, new indication
etanercept (ENBREL®)
filgrastim (NEUPOGEN®), new indication
levonorgestrel releasting intrauterine system (MIRENA®)
moxifloxacin (AVELOX®)
norethindrone acetate ethinyl estradiol/FemHRT®)
perindopril (COVERSYL®), resubmission
pioglitazone (ACTOS®)
pramipexole (MIRAPEX®), resubmission
riluzole (RILUTEK®)
risedronate (ACTONEL®), new indication
testosterone (ANDRODERM®)
tizanidine (ZANAFLEX®), resubmission